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RESEARCH ARTICLE

Enhancing participant understanding and ethical considerations in clinical trial biospecimen research: Insights from an oncology setting in India

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Abstract

This study explores the KAP of clinical trial participants on the use of surplus biospecimens for future research in Indian oncology trials. A hospital-based prospective study was conducted among 112 oncology clinical trial participants. Non-probability purposive sampling technique was used to recruit the participants. This study captured their socio-demographic information and pre and post-KAP assessment by using self-administered questionnaires and its highlights ethical concerns and the lack of global guidelines. The main goal is to understand participants' understanding and opinions on sample collection, utilization, and storage, as well as the ethical implications. SPSS software used for statistical analysis to evaluate pre and post-intervention KAP scores using frequency, percentage, mean difference, standard deviation, and applied paired t-test and Wilcoxon signed ranks test to assess Different KAP Levels. The study analyzed knowledge, attitude, and practice levels among oncology clinical trial participants using statistical tests. Pre-test to post-test comparisons showed significant increases in knowledge ($p < 0.001$, Wilcoxon Signed Ranks Test), attitude ($p < 0.001$, paired-samples t-test), and practice ($p < 0.001$), highlighting the intervention's effectiveness. This study highlights the effectiveness of interventions in improving the knowledge, attitude, and practice (KAP) of oncology clinical trial participants in India regarding the use of surplus biospecimens, emphasizing the importance of standardized guidelines in global oncology trials.

Keywords: Bioethics, Clinical trial participants, Surplus biospecimens, Knowledge, Attitude, Practice.

Introduction

Biospecimen research plays a crucial role in advancing oncology trials in India. Researchers can gain valuable insights into the genetic and molecular mechanisms underlying cancer development and progression by studying biological samples such as blood, tissue, and DNA (Al-Hussaini, M., *et al.* Al, 2014). This information is essential for developing personalized treatment strategies and improving patient outcomes. However, conducting biospecimen research in oncology trials raises important ethical considerations. Researchers must ensure that participants provide informed consent for collecting and using their biological samples and that their privacy and confidentiality are protected. (Echeverri, M., *et al.*2018, Sutton, *et al.*2018, Kapp M. B. (2006).). Additionally, researchers must adhere to strict guidelines for storing and handling biospecimens to ensure their integrity and reliability. (Schafer, *et al.,* 2007, Baer *et al.,* 2010). By illuminating the ethical considerations surrounding biospecimen research in Indian oncology trials, we can empower researchers, clinicians, and policymakers to make informed decisions that prioritize patient welfare and uphold ethical standards. Through transparent communication and collaboration, we can ensure that biospecimen research in oncology trials in India is conducted ethically and responsibly, ultimately leading to improved cancer care and outcomes for patients.

The interpretation of regulations concerning human tissue research can pose difficulties for pathologists and researchers (Kapila *et al.* 2016, Lacaze *et al.,* 2017). Biomaterials play a crucial role in research, and each study procedure should include information on their usage, storage, and the significance of samples in research. Warner

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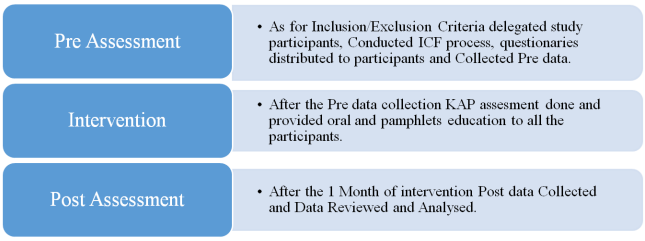

Sources: the present doctoral research shows that the by using descriptive statistics analyzed different demographic variables distribution and KAP levels of the clinical trial participants.

Flowchart 1: Study procedure

et al. 2018, Matimba *et al.* 2019. In our study, we conducted a KAP study on the opinions of clinical research participants regarding the utilization of surplus biospecimens. All participants were asked about surplus biospecimen research, its applications, and their views on the collection, utilization, and storage of human biomaterials in clinical research. Clinical trial participants (CTPs) play a significant role in the field of clinical trials. Our research objective is to evaluate the knowledge, attitudes, and practices related to leftover samples and data reuse for future research. There are ethical dilemmas involved in preparing, implementing, and conducting research on leftover biospecimens in clinical trials, such as optional research on leftover samples, data reuse, optional consent, storage and utilization of biomaterial sample data (including genetic information), as well as the return of research results and benefits to study participants (Moodley *et al.,* 2014).

In India, there are guidelines from the Indian Council of Medical Research (ICMR) for collecting and storing biological samples and leftover sample data. Mathur *et al.* 2019. However, no specific international guidelines exist to standardize or minimize ethical challenges, consent-related issues, and decisions regarding leftover samples in research.

Materials and Methods

This interventional study, conducted over a year at a tertiary care Hospital in Belagavi, received ethical approval from the Ethical Committee of KLE College of Pharmacy, Belagavi Karnataka, on July 29, 2021 (Ref.No: KAHER/EC21/22/021), and was registered under the Clinical Trial Registry in India with the reference CTRI/2021/11/038332 (Registered on: 30/11/2021). Oncology clinical trial participants were included by using a non-probability purposive sampling technique was used to recruit the participants, and closed-ended questionnaires were utilized. Informed consent was obtained from all participants before enrolment, and those unwilling to participate were excluded. The study enrolled 112 participants from December 1, 2021, to February 22, 2023. Statistical analysis involved using KAP questionnaires, with data collected and analyzed using Excel. Descriptive statistics and tests such as paired t-tests and Wilcoxon signed ranks test were employed to determine the significance between pre-test and post-test scores.

Table 1: Demographic profile of clinical trial participants

Demographic characteristics	*Variables*	*n(112)*	*100%*
Age	18–30	12	10.7
	31–42	47	42
	43–55	48	42.9
	56–68	5	4.5
Sex	Male	50	44.6
	Female	62	55.4
Religion:	Hindu	101	90.2
	Muslim	10	8.9
	Christian	1	0.9
Education/ Qualification	Illiterate	15	13.4
	Primary/Secondary school	57	50.9
	PUC	9	8
	Graduation	23	20.5
	Masters	8	7.1
Employment:	Self-employ	15	13.4
	Former	21	18.8
	Labor	14	12.5
	Govt. employ	7	6.3
	House wife	43	38.4
	Students	8	7.1
	Others specify	4	3.6
Type of Cancer	Breast cancer	38	33.9
	Cervix cancer	8	7.1
	Prostate cancer	12	10.7
	Tongue cancer	2	1.8
	Lung cancer	6	5.4
	Oral cancer	6	5.4
	Uterus cancer	1	0.9
	Esophageal cancer	11	9.8
	Colon cancer	4	3.6
	H/N cancer	18	16.1
	Stomach cancer	1	0.9
	Buccal mucosa	3	2.7
	Rectum cancer	1	0.9
	Thyroid cancer	1	0.9
	Total	112	

Study Procedure Flow Chart

Study procedure Flowchart 1.

Table 1 shows the demographic variables of the clinical trial participants.

Table 2: Shows the pre & post analysis of knowledge levels among oncology clinical trial participants by using [a] Wilcoxon signed ranks test

Levels of Knowledge	*Pre-Test*	*Post-Test*	*Mean Diff*	*t-Value*	*p-value*
	No%	*No%*			
Low level (<50%)	88 (78.6)	4 (4.6)			
Average level (50-75%)	19 (17)	19 (17)	-	9.07	<0.001[a]
High level (>=76-100%)	5 (4.5)	89 (79.5)			
Total	112 (100)	112 (100)			

Table 3: Shows the pre & post analysis of attitude levels among oncology clinical trial participants by using [b] paired-samples t-test

Levels of attitude	*Pre-test*	*Post-test*	*Mean diff*	*t-Value*	*p-value*
	No%	*No%*			
Low level (<50%)	26 (23.2)	59 (52.7)			
Average level (50–75%)	86 (76.8)	51 (45.5)	3.24	5.57	<0.001[b]
High level (>=76–100%)	0 (0)	2 (1.8)			
Total	112 (100)	112 (100)			

The demographic characteristics of the surveyed population are presented across several variables such as age, gender, religion, employment, education and type cancer diagnosis. In terms of age distribution, the majority of respondents fall within the 31 to 42 (42%) and 43 to 55 (42.9%) age brackets, followed by 18 to 30 (10.7%) and 56 to 68 (4.5%). As per gender, the sample consists of 44.6% males and 55.4% females. Religious affiliation shows a predominance of Hindus (90.2%), followed by Muslims (8.9%) and Christians (0.9%). As per education levels vary, with the highest proportion having attended primary or secondary school (50.9%), followed by graduation (20.5%), illiterate (13.4%), PUC (8%), and master (7.1%) and employment status showcases a diverse range, with housewives constituting the largest group (38.4%), followed by former employees (18.8%), self-employed (13.4%), labourers (12.5%), students (7.1%), government employees (6.3%), and others (3.6%). Lastly, the types of cancer reported by the respondents indicate a significant prevalence of breast cancer (33.9%), followed by head and neck cancer (16.1%), prostate cancer (10.7%), esophageal cancer (9.8%), and other types with lower percentages. The total sample size was 112 individuals. These demographic insights provide a comprehensive understanding of the characteristics of the population under study, crucial for targeted healthcare interventions and policy formulation. (These results showed in Table 1).

Table 2 shows the pre & post analysis knowledge levels among oncology clinical trial participants.

A detailed analysis of participants' pre- and post KAP levels in a clinical trial using Wilcoxon Signed ranks test & paired-samples T-test. The table is divided into three levels: low level (<50%), average level (50–75%), and high level (>=76–100%) along with mean differences and t-values and *p-values*. The "Mean Diff" column indicates the mean difference between pre-and post-test values for each level. The "*p-value*" column displays the statistical significance of the difference.

A detailed analysis of the knowledge levels of participants pre and post their involvement in a clinical trial, as assessed through a Wilcoxon Signed ranks test. The table is structured to compare the pre-test and post-test results, including the number and percentage of participants at different levels of knowledge. Prior to the trial, the majority of participants had a low level of knowledge (78.6%), while only a small portion had an average level (17%) and even fewer had a high level (4.5%). Following the trial, there was a significant shift in knowledge levels, with a substantial decrease in the number of participants with a low level (down to 4.6%) and a notable increase in those with a high level (up to 79.5%). Interestingly, the number of participants with an average level remained the same pre and post-trial. The mean difference between pre-test and post-test knowledge levels was 9.07, indicating a substantial improvement. The statistical analysis revealed a highly significant *p-value* of less than 0.001, suggesting that the observed changes in knowledge levels are unlikely to have occurred by chance. This analysis underscores the clinical trial's effectiveness in enhancing participants' knowledge, particularly in elevating them from a low to a high level of understanding regarding the subject matter under investigation.

Table 3 shows the pre & post analysis attitudes levels among oncology clinical trial participants.

A detailed analysis on the attitudes of participants pre and post on clinical trial participants, conducted using a paired-samples T test. In the pre-test, 23.2% of participants exhibited a low level of attitude, which increased to 52.7% in the post-test, indicating a significant positive shift. Conversely, the percentage of participants with an average level of attitude decreased from 76.8% in the pre-test to 45.5% in the post-test. Notably, initially at 0%, the high-level attitude category showed a minor increase to 1.8% post-test. The mean difference between pre-test and post-test attitudes was 3.24, with a corresponding *p-value* of less than 0.001, suggesting a statistically significant change. These findings underscore the impact of the clinical trial on participants' attitudes, revealing a notable improvement.

Table 4 shows the pre & post analysis practice levels among oncology clinical trial participants.

The table highlights suggesting a substantial impact of the clinical trial on participants' practices. Specifically, the low-level practice group saw a considerable increase to 36 (32.1%) post-intervention, the average-level group

Table 4: Shows the pre & post analysis of practice levels among oncology clinical trial participants by using [b] paired-samples t-test

Levels of practice	*Pre-test*		*Mean Diff*	*t-value*	*p-value*
	No%	*No%*			
Low level (<50%)	105 (93.8)	36 (32.1)			
Average level (50–75%)	7 (6.3)	60 (53.6)	5.25	17.26	<0.001[b]
High level (>=76–100%)	0(0)	16 (14.3)			
Total	112 (100)	112 (100)			

increased to 60 (53.6%), and the high-level group increased to 16 (14.3%). These findings underscore the effectiveness of the intervention in enhancing participants' practice levels across all categories. A significant improvement in practice levels post-intervention, as indicated by the *p-value* (<0.001).

Discussion

The present research the crucial issue of ethical considerations and practices concerning the utilization of surplus biospecimens in oncology clinical trials in India. It starts by highlighting the importance of biospecimen research in advancing oncology, emphasizing the need for ethical guidelines due to the potential implications for patient welfare and privacy. Lack of uniformity in guidelines across countries underscores the necessity for comprehensive frameworks tailored to local contexts.

The research papers thoroughly examine ethical issues related to HBMs for research, discussing regulatory structures, obstacles, and resolutions in different settings. Meslin *et al*. (2004), focuses on general ethical concerns, including regulations, misuse of genetic data, economic factors, and public awareness, underscoring the pivotal role of HBMs in advancing medicine. It suggests that while the current regulatory landscape may fall short in addressing privacy and confidentiality issues, reforms and education could mitigate these challenges Kapp M. B. (2006). The article discusses informed consent and confidentiality in the US regulatory system, focusing on challenges in obtaining genuine consent for future research and the debate over specific *versus* generic consent. Schafer *et al.* (2007), provide a comprehensive framework for the ethical utilization of human tissues in biomedical research. Their guidelines prioritize patient safety, and autonomy, and foster collaboration between pathology institutions and research initiatives in Switzerland. Baer *et al.* (2010), conducted research on biospecimen collection in clinical trials, emphasizing the importance of understanding the reasons for collection, promoting participation, and addressing ethical concerns. These papers offer a comprehensive view of the ethical aspects of research involving human biological materials (HBMs), highlighting the need for thoughtful deliberation and continuous communication. In summary, these study findings not only assist us in refining our research focus but also aid in the identification of ethical dilemmas and concerns related to the use of biospecimen samples. This knowledge allows us to develop interventions aimed at enhancing research outcomes, advocate for improved ethical frameworks, and contribute to the broader scientific community's understanding of ethical considerations in biospecimen research.

Peppercorn, *et al*., (2020) conducted a survey among 240 cancer patients at an academic medical center to investigate their attitudes and preferences towards cancer research and biospecimen donation. The results revealed a strong willingness (94%) among participants to donate tissue for research, with the majority expecting their donated tissue to be utilized for scientifically significant research while keeping their health information confidential. Moreover, most patients supported the continuation of research even in cases where specific consent for proposed bio-bank research was not clearly outlined in the informed consent document. Younger patients tended to show more approval for the broad use of biospecimens without specific consent compared to older patients. In the current investigation, it was observed that 23.2% of participants exhibited a low level of attitude during the pre-test. However, this figure increased to 52.7% in the post-test, indicating a significant improvement in their utilization of samples.

Yip *et al*., (2018), the research involved qualitative interviews with oncology patients and healthcare professionals from five Australian hospitals to study perceptions and experiences of bio-banking consent. Patients were asked to consent to bio-banking in the context of a clinical trial or future research. Among the 22 patients, themes emerged including the perception of bio-banking as simple, motivations driven by altruism or scientific curiosity, trust in healthcare providers and institutions, preference for opt-in or opt-out consent models, and the importance of emotional support and timing during the consent process. Patients generally preferred an initial opt-in approach with the ability to opt-out later. Our findings suggest that participants had a positive outlook on using samples for future research, but stressed the importance of following regulations and ethical guidelines for handling these samples respectfully. By addressing these concerns, researchers can create a supportive environment for using samples in future studies.

Gao *et al*., (2022) examined attitudes toward bio-bank sample donation *via* structured questionnaires using different promotional materials: picture-based, text-based, and a lecture. Pre- and post-session responses revealed increased willingness to donate, with the lecture being most effective. Participants with medical backgrounds were more inclined to donate, citing altruism and aiding research, while

privacy concerns posed obstacles. In our study, we observed that individuals with a higher literacy level demonstrated a more positive and extensive understanding of the potential utilization of leftover samples in future research compared to those with a lower literacy level.

Buhmeida *et al*., (2022), in a study conducted in Makkah province, 636 healthcare providers were surveyed using a structured questionnaire. The results showed that the mean bio bank knowledge score was 3.5 out of 7. Approximately one-third of the participants were familiar with the Human Genome Project and 'bio-bank'. Overall, the participants displayed a positive attitude towards biomedical research. Concerns regarding misuse and confidentiality were identified as major barriers to donation. Our study also revealed significant improvements in pre-test and post-test knowledge levels, with scores of 9.07. Similar concerns were raised regarding the future research of samples, the final destination of samples, the authority of leftover samples, autonomy, privacy, and the proper use of samples in accordance with ethical standards.

Ma *et al*., (2012), conducted at Shanghai and surveyed 648 hospital patients and 492 members of the general public. Results showed 64.7% were willing to donate biosamples, with 16.7% wanting the option to withdraw. Trust in medical institutions was low at 42.3%, affecting donation willingness. Only 12.1% agreed to future research without specific consent. Hepatitis B carriers were less willing to donate (32.1 *vs*. 64.7% for non-carriers). Lack of trust may lead to desire for control over sample usage, emphasizing the need for specific informed consent in China. In our study, we conducted pre and post surveys to assess donation attitudes and perspectives on using leftover samples in future oncology research. The pre-test showed poor response, but there was a significant improvement after the intervention. Initially, most participants had low knowledge (78.6%), some had average knowledge (17%), and few had high knowledge (4.5%). After the trial, there was a notable shift in knowledge levels, with low knowledge decreasing to 4.6% and high knowledge increasing to 79.5%. Attitudes also changed, with low levels increasing to 52.7% and average levels decreasing to 45.5%. The mean difference in attitudes was 3.24, with a *p-value* below 0.001. Practice groups also saw increases in attitudes post-intervention.

Conclusion

The analysis of knowledge, attitudes, and practices (KAP) levels post-intervention in a clinical trial demonstrated significant improvements, indicating the efficacy of the intervention in enhancing participants' understanding, perspectives, and attitudes. These results underscore the importance of ethical research conduct and its potential impact on patient care and outcomes. The study revealed a notable KAP gap among participants initially, which was effectively addressed through educational interventions such as educational tools, oral explanations, and advertisements, leading to enhanced awareness regarding leftover biospecimen research. Furthermore, the study emphasizes the significance of educational interventions in improving awareness about the collection, utilization, and storage of biospecimen samples for future research. The need for uniform guidelines and consent forms for future research is highlighted to enhance participant willingness for such studies. Moving forward, continuous refinement of ethical guidelines and practices, in alignment with the evolving landscape of oncology research and technological advancements, is crucial. Collaborative efforts involving researchers, clinicians, policymakers, and ethical committees are essential to ensure ethical conduct and maximize the benefits of biospecimen research in oncology clinical trials. Prioritizing patient welfare and upholding ethical standards can significantly contribute to advancing cancer care and improving patient outcomes in India and globally.

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